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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/672,626

09/26/2003

Amy F.T. Arnsten

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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

05/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/672,626	Applicant(s) ARNSTEN ET AL.	
	Examiner Renee Claytor	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,10,12,14 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,10,12,14 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed on 4/22/2008 have been fully considered. Upon further consideration and the amendments presently made in the claims, it was determined that a new grounds of rejection is necessary. Therefore, the Examiner is re-opening prosecution.

Claim Rejections -35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 10, 12, 14 and 18-20 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, there is no teaching in the specification of what a solvate or polymorph of chelerythrine is.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating learning and memory tasks and mania by administration of chelerythrine, does not reasonably provide enablement for preventing a subject from developing a CNS disorder by administering chelerythrine. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention: The rejected claim 20 is drawn to a method comprising preventing a subject from developing a CNS disorder by administering a pharmaceutical composition.

(2) The state of the prior art: The state of the art regarding treating bipolar disorder is high. However, the state of the art regarding prevention of bipolar disorder is underdeveloped.

(3) The relative skill of those in the art: The relative skill of those in the art is high.

(4) The breadth of the claims: Claim 20 embraces a method comprising preventing a subject from developing bipolar disorder by administering to a subject a pharmaceutical composition.

(5) The amount of guidance or direction presented: In the instant case, working examples are presented for treating manic episodes and learning and memory tasks with chelerythrine in the specification on pages 19-23 in which chelerythrine was shown to increase performance on learning and memory tasks as well as improve the stress response (involving manic episodes). However, there are a lack of working examples presented in the specification as filed showing how to prevent bipolar disorder. Note that lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP § 2164.

(6) The presence or absence of working examples: Applicant does not provide any working examples for the prevention of bipolar disorder.

(7) The quantitation of experimentation necessary: Claim 20 reads on a method comprising preventing bipolar disorder by administration of a pharmaceutical composition. As discussed above, the specification provides examples for treating learning and memory disorders and bipolar disorders but the specification fails to provide support for the prevention of bipolar disorder. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F.3d at 1366 states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent

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protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Claim Rejections – 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 10, 18, 19, 20 rejected under 35 U.S.C. 102(b) as being anticipated by Birnbaum et al. (Society for Neuroscience Abstract, 2000).

Birnbaum et al. teach that local intra-PFC infusion of chelerythrine reversed stress-induced working memory impairment caused by phenylephrine in rats. The authors conclude that blockade of PKC may help to restore cognitive function during stress (see whole document).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Birnbaum et al. (Society for Neuroscience Abstract, 2000) in view of He et al. (US Patent 6,815,450).

Birnbaum et al. teach animal models of working memory impairment and bipolar disorder as being treatable by local injection of chelerythrine.

Birnbaum et al. does not contemplate other modes of administration of chelerythrine.

He et al. teach chelerythrine as a PKC inhibitor and teach in situ applications. He et al. teach that for the in situ applications, compositions comprising the PKC inhibitor may be administered by any effective route compatible with therapeutic activity of the compositions and patient tolerance (Col. 4, lines 3-6). It is further contemplated by the teachings of He et al. that the inhibitor is administered in a pharmaceutically acceptable excipients such as saline or other medium in an effort to form pharmaceutically acceptable compositions and dosage units that may be included in capsules, pills, etc. which contemplates other routes of administration other than local injection (i.e., systemic infusion and oral).

Accordingly, it would be obvious to a person of ordinary skill in the art to treat bipolar disorder or working memory deficit with chelerythrine because of the teachings of Birnbaum et al. that chelerythrine reverses stress-induced working memory impairment. One would be motivated to modify the teachings of Birnbaum et al. to include other modes of administration, including oral administration, in an effort to effectively administer chelerythrine to a patient in need of restoration of normal cognitive function.

Conclusion

No claims allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

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/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617